REMARKS

Status

Claims 52 and 56-83 were pending in this Office Action. The present response cancels all pending claims and substitutes therefor new claims 85-111.

The Office Action

In the Office Action mailed March 19, 2010, all claims were rejected under 35 U.S.C. §103 in view of U.S. Patent 4,669,477 of Ober taken either singly or in combination with other prior art. Specifically, claims 52, 56-59, 62, 63, 65, 67-70, 72 and 76-79 were rejected under 35 U.S.C. §103 as being unpatentable over Ober. Claims 52, 56-59, 62-65, 67-70, 72, 77, 78 and 80 were rejected under 35 U.S.C. §103 in view of the combination of Ober and U.S. Patent 6,270,466 of Weinstein. Claim 60 was rejected under 35 U.S.C. §103 either over the combination of Weinstein and Ober taken in view of U.S. Patent 6,636,763 of Junker or in view of the combination of Ober and Junker. Claim 61 was rejected under 35 U.S.C. §103 over the combination of Weinstein, Ober, and Junker taken further in view of U.S. Patent 4,993,423 of Stice. Claims 64 and 66 were rejected under 35 U.S.C. §103 over the combination of Weinstein and Ober taken in view of U.S. Patent 5,368,043 of Sunouchi or alternatively over the combination of Ober and Sunouchi. Claims 71, 73 and 74 were rejected under 35 U.S.C. §103 over the combination of Weinstein and Ober taken further in view of the publication of Lavigne or alternatively over the combination of Ober and Lavigne.

Claim 75 was rejected under 35 U.S.C. §103 over the combination of Weinstein and Ober taken further in view of U.S. Patent 6,306,100 of Prass or alternatively over the combination of Ober and Prass. Claims 76 and 81 were rejected under 35 U.S.C. §103 over the combination of Weinstein and Ober taken further in view of U.S. Patent Application Publication 2004/0068196

of Massicotte or alternatively over the combination of Ober and Massicotte. Claims 82 and 83 were rejected under 35 U.S.C. §103 over the combination of Weinstein and Ober taken further in view of U.S. Patent 5,877,444 of Hine or alternatively over the combination of Ober and Hine.

In addition, claims 52 and 62 were rejected under 35 U.S.C. §112, first paragraph, and claims 52, 61, 68 and 74 were rejected under 35 U.S.C. §112, second paragraph. In addition, particular objections were made to the drawings and to claims 52, 68, 72 and 83.

Applicant thanks the Examiner for the Office Action and for the thorough explanation of the basis of the rejections.

The Newly Presented Claims Overcome All Rejections and Objections and Are Patentable

The newly presented claims overcome all prior objections and rejections and fully describe and recite features of the present invention which are neither shown nor suggested in the prior art. As background to the following remarks, Applicant will briefly recapitulate the principles of the present invention.

The present invention is directed to systems and methods for detecting the onset of bruxism and providing a feedback signal which enables a patient to control the condition. The system of the present invention is operative to establish a very accurate threshold sensitivity level for the control of the feedback signal and as such represents a significant improvement over prior art of record in this patent application. In the present invention the feedback signal is generated by a multi-step process in which (1) a bite force signal is determined; (2) a signal indicative of typical, non-bite, jaw motion is determined; and (3) a threshold is calculated on the basis of these two determinations such that the threshold represents some percentage (typically 3-20%) of the bite force, with the proviso that this threshold is greater than the maximum of the typical jaw

muscle activity signal. As detailed in the present application, setting of the threshold by this procedure assures that the feedback signal will be generated only in response to undesired jaw motion (bruxism). This is in contrast to prior art systems such as that of the Ober reference wherein the threshold is merely set as being some preselected level of jaw muscle activity.

The presently presented claims include independent claim 85 directed to an apparatus for detecting bruxism and this claim specifically recites steps 1-3 as described above. Claims 86-108 depend from claim 85. The new claim set also includes independent claim 109 which basically tracks claim 85 and in that regard also recites steps 1-3 above. Claims 110 and 111 depend from claim 109.

In the prior prosecution of this application, the Ober '477 patent was the base reference for all rejections, and Applicant respectfully submits that the presently pending claims are patentable thereover. The Ober patent shows a very simple system for controlling bruxism. The Ober system operates to measure the level of jaw activity and provides a feedback signal if this level exceeds some **manually input threshold**. The setting of the threshold is accomplished through the use of a simple circuit which essentially sets the "sensitivity" of the system. No parameters for the establishment of the threshold are detailed, and the Ober system does not operate to determine bite force, typical non-bite jaw motion, nor does it calculate or otherwise establish any threshold which represents some percentage of the bite force with the proviso that this threshold is greater than the maximum of typical jaw muscle activity. Essentially, the Ober system uses a "trial and error" method to set the threshold sensitivity. Systems of the Ober type are generally inadequate insofar as they either provide too many false positive signals or fail to provide signals indicative of bruxism. Hence, patient compliance in the use of Ober-type systems is generally poor.

The Ober apparatus includes a control circuit 14 having a signal processor 26, a threshold trigger 28, and a threshold value circuit 30, as seen in Fig. 1 of the reference. The signal processor 26 processes signals received from the inputs of the electrodes 20 attached to a patient's jaw. The threshold trigger 28 receives the processed input signals and compares to a threshold value signal produced by the threshold value circuit 30 to determine whether an electronic stimulation signal is applied to the patient's jaw. In sharp contrast to the claimed invention, the only input into the threshold value circuit 30 is the threshold control 32. As seen in Fig. 1 of the Ober patent, the threshold control 32 is merely a manually operated dial.

Further, the Ober patent states at column 3, lines 3-6:

> The threshold signal produced by the threshold value circuit 30 is preferably a voltage signal having a magnitude proportional to a predetermined level of jaw activity. This signal is compared directly to the processed input signal by threshold trigger circuit 28.

Further still, in the present Office Action section 12, page 8, line 20, the Examiner states:

> Ober discloses the manual adjustment of the threshold via the threshold control (32), but does not disclose an automatic determination and adjustment of the threshold.

Accordingly, there is no implicit or explicit indication that the threshold signal is nothing more than a manually adjusted value.

The Examiner has addressed Applicant's previous remarks regarding the Ober patent in the present Office Action, in section 28 commencing at page 22, in which the Examiner acknowledges that:

> Ober fails to teach a muscle monitoring apparatus to calculate a threshold value for outputting a feedback signal, based upon separately measured normally occurring muscle activity and a maximal muscle activity.

Despite recognizing this significant distinction between Ober and the present invention, the Examiner ignores this stated fact and goes on to characterize the distinction between the present invention and that of Ober as being merely "the replacement of a manual operation with an automatic operation". In the second paragraph of section 28, the Examiner acknowledges that Ober utilizes a person to determine and adjust the threshold of the device and characterizes Applicant's three-step process as being "the replacement of a manual operation with an automatic operation [and hence] a mere design consideration within the skill in the art."

While Applicant agrees with the Examiner that the mere automation of a previously manual process is *per se* obvious and unpatentable, such is not the case at the present. While both Ober and the present invention operate to set a threshold of sensitivity, the manner in which the threshold is set in Ober and in the present invention differs significantly. Likewise, the accuracy and value of the system of the present invention greatly exceeds that of Ober. Language in the Ober patent at column 3, lines 4-12 makes very clear that sensitivity of the device is manually set at **some preselected value chosen without regard to any measurement of bite force and/or normal jaw muscle activity**. The present invention is not merely the automation of the sensitivity setting of the Ober process. Instead, the present invention represents a significant improvement over the Ober device and method insofar as the present invention establishes a threshold level which is determined from **two sets of separately measured parameters** and which gives a significantly improved result in the operation of the device insofar as false triggering of the feedback signal by normal jaw motion, such as would occur during sleep, will not occur.

Although the purposes of the different operations are the same, i.e. establishing a threshold value for output of a feedback signal, the resulting outcomes of the operations are

entirely different. The manual adjustment of the threshold control 32 of the Ober patent results in uncertainty and randomness of how the threshold is adapted to the specific user, whereas the setting of the threshold according to the present invention provides an accurate adjustment and adaptation to the individual user because the adjustment is based on and validated against actual physical measurements. The result of the present invention is that the feedback signal is provided only in response to actual bruxism events, which is important as the anti-bruxism device is mostly worn during sleep. However, with the Ober device the user cannot be sure that the manually adjusted threshold level is suitable for responding to bruxism events occurring during the night as the threshold adjustment is not validated against measurements of the user.

The Examiner cannot dismiss this feature of the present invention as being the mere replacement of manual operation with automatic operation given the fact that the prior art does not show or suggest the determination of the threshold on the basis of data obtained through the steps of the present invention. It is significant that use of the present invention achieves benefits neither suggested nor anticipated by the prior art, and such "unanticipated benefits" are an indicator of nonobviousness.

Further on in section 28, in the partial paragraph beginning on page 23, the Examiner makes the statement that "Applicants further argue Ober does not teach normally occurring muscle activity and maximal muscle activity." This statement evidences the Examiner's misunderstanding of the basic nature of the present invention insofar as the Examiner appears to be arguing that since Ober adjusts the sensitivity of the device to accommodate muscle activity levels of various individual users, Ober must be differentiating normally occurring muscle activity and biting force. While it is true that Ober wishes to provide a feedback signal only in the case of bruxism, Ober uses a simple sensitivity setting made without any reference to specific

parameters in a blind attempt to control operation of the system. This is in contrast to the multi-parameter threshold employed in the present invention.

In summary, the Ober prior art, while directed to systems for monitoring and controlling bruxism, merely represents a first generation approach in which a threshold of sensitivity is manually set through a trial and error process. In contrast, the present invention represents a second generation of system in which a threshold is automatically and empirically determined based upon a multi-parameter analysis. The distinction between the two is not the automation of a manual process but implementation of a fundamentally different process which achieves superior and unanticipated results. Specifically, the Ober patent fails to disclose 1) a sensor system operable to measure a first level of muscular activity associated with a level of biting force and to generate a first signal corresponding thereto, 2) a sensor system operable to measure a second level of muscular activity associated with normally occurring jaw activity and to generate a second signal corresponding thereto, and 3) a signal processor which is operable to receive the first and second signals and calculate a threshold level of muscular activity of the jaw which is less than the first level and more than the second level.

The present invention, as now claimed, is patentable over the Ober prior art. In view of the general inapplicability of the base Ober reference, Applicant respectfully submits that the claims at issue are also patentable over the secondary and tertiary references. Furthermore, in view of the new claims presented herewith, all other objections and rejections are likewise overcome. The claims are in condition for allowance.

Request for Interview

Applicant thanks the Examiner for the detailed response to prior arguments presented in section 28 of the Office Action. This response makes very clear that, heretofore, the Examiner

has not been made properly aware of the distinction between the process of the present invention and that of the prior art as well as the advantages and improvements attendant upon the use of the present invention. Applicant apologizes for any lack of clarity in prior interchanges with the Examiner.

If the Examiner feels that it would be beneficial to discuss any aspects of this response in detail, Applicant's attorney would be most pleased to speak with the Examiner at the Examiner's convenience.

New Contact Information

Applicant's attorney directs the Examiner's attention to the fact that responsibility of the prosecution of this application has been transferred to the attorney listed below. In order to expedite matters, all correspondence should be directed to the undersigned attorney.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 07-1180.

Dated:

Respectfully submitted,
By: /Ronald W. Citkowski/
Electronic Signature
Ronald W. Citkowski
Registration No.: 31,005
GIFFORD, KRASS, SPRINKLE, ANDERSON & CITKOWSKI, P.C.
2701 Troy Center Drive, Suite 330
Post Office Box 7021
Troy, Michigan 48007-7021
(248) 647-6000
(248) 647-5210 (Fax)
Attorney for Applicant